REMARKS

In the Office Action, the Examiner withdrew claims 34-45, 47, 50-51, and 53 from consideration as being drawn to a non-elected invention with no allowable generic or linking claim. The Office Action rejected claims 1, 31-33, 46, 48-49, 52, and 54 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Office Action rejected claims 46 and 52 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps. The Office Action rejected claims 1, 31-33, 46, 48-49, 52, and 54 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. The Office Action rejected claims 1, 31-33, 48, and 54 under 35 U.S.C. § 102(b) as being anticipated by Non-Patent Literature identified as "Neurourol. and Urodyn. 19:279-287, 2000" written by Chancellor et al. ("Chancellor"). The Office Action rejected claims 1, 31-33, 46, 48-49, 52 and 54 under 35 U.S.C. § 102(e) as being anticipated by Chancellor. The Office Action rejected claims 1, 31-32, 46, 48, 52, and 54 under 35 U.S.C. § 103(a) as unpatentable over Chancellor in view of Non-Patent Literature identified as "BJU International 89(3):298-302, 2002" written by Yiou et al. ("Yiou") in further view of Non-Patent Literature identified as "Urology 57:826-831, 2001" written by Yokoyama et al. ("Yokoyama"), in still further view of U.S. Patent 5,942,437 issued to Sanberg et al. ("Sanberg").

In this Amendment, Applicant has amended claims 1, 32, 46, 48, 52, and 54. Applicant has also amended withdrawn claims 37, 47, and 53. Applicant has canceled claims 49 and 51. Applicant has not added any claims. Applicant does not surrender any equivalents to any amended elements or limitations of any amended claim. Accordingly, claims 1, 31-33, 46, 48, 52, and 54 will be pending after entry of this Amendment.

I. REJECTION OF CLAIMS 1, 48, AND 54 (AND DEPENDENTS) UNDER 35 U.S.C. §112, 2nd PARAGRAPH AS BEING INDEFINITE

The Office Action rejected claims 1, 48, and 54 as being indefinite for not reciting the subject to whom the myoblasts are being administered. Applicant has amended claims 1, 48, and 54 to recite "human" rather than "mammal" and "administering to said human myoblasts obtained…". Accordingly, Applicant respectfully requests that the rejections, under §112, 2nd paragraph as indefinite, of claims 1, 48, 54 and their dependent claims be withdrawn.

II. REJECTION OF CLAIM 32 UNDER 35 U.S.C. §112, 2nd PARAGRAPH AS BEING INDEFINITE

The Office Action rejected claim 32 as being indefinite for containing the limitation "selecting cells and amplifying cells" and because "cells" being amplified are broader than the "myoblasts" of claim 1. Applicant has amended claim 32 to delete the limitation "selecting" and changing "amplifying cells" to "amplifying myoblasts". Accordingly, Applicant respectfully requests that the rejection, under §112, 2nd paragraph as indefinite, of claim 32 be withdrawn.

III. REJECTION OF CLAIMS 46 AND 49 UNDER 35 U.S.C. §112, 2nd PARAGRAPH AS BEING INDEFINITE

The Office Action rejected claims 46 and 49 as being indefinite for containing the limitation "performing cell differentiation" Applicant has amended claim 46 to delete the limitation "performing cell differentiation" and canceled claim 49. Accordingly, Applicant respectfully requests that the rejections, under §112, 2nd paragraph as indefinite, of claims 46, and 49 be withdrawn.

IV. REJECTION OF CLAIMS 46 AND 52 UNDER 35 U.S.C. §112, 2nd PARAGRAPH AS BEING INDEFINITE

The Office Action rejected claims 46 and 52 as being indefinite for containing the limitation "performing a characterization on said myoblasts" without further limitation of the characterization. Applicant has amended claims 46 and 52 to add that the characterization is performed "with cell cycle markers". Accordingly, Applicant respectfully requests that the rejections, under §112, 2nd paragraph as indefinite, of claims 46, and 52 be withdrawn.

V. REJECTION OF CLAIMS 46 AND 52 UNDER 35 U.S.C. §112, 2nd PARAGRAPH AS BEING INCOMPLETE

The Office Action rejected claims 46 and 52 as being incomplete for omitting essential steps, specifically, thawing the frozen myoblasts prior to administration. Applicant has amended claims 46 and 52 to recite "thawing the frozen myoblasts prior to administration". Accordingly, Applicant respectfully requests that the rejections, under §112, 2nd paragraph as incomplete, of claims 46, and 52 be withdrawn.

VI. REJECTION OF CLAIMS 46 AND 52 UNDER 35 U.S.C. §112, 1st PARAGRAPH AS LACKING ENABLEMENT

The Office Action rejected claims 1, 31-33, 46, 48-49, 52, and 54 as failing to comply with the enablement requirement for several reasons detailed below.

First, the Office Action rejected the breadth of the claims, because they encompass treatment of mammals (the Office Action cites that there are 5,500 species of mammals). Accordingly, Applicant has amended the claims to recite that the treatment is of humans. Applicant respectfully request that this ground of rejection be withdrawn.

Second, the Office Action rejected the claims as not disclosing how to administer the myoblasts so as to achieve a clinically meaningful and therapeutic result. Applicant respectfully submits that the experiments described in the specification show that the methods according to the invention enable the production of a substantial amount of myoblasts. That is, the culturing steps described enable one of ordinary skill in the art to produce the recited myoblasts. Furthermore, the produced myoblasts can then be used for further therapeutic use.

Applicant respectfully submits that the specification enables one of ordinary skill in the art to administer the myoblasts therapeutically. The Office Action cites later research by Applicant as stating that the "optimal number of muscle precursor cells to be injected into a recipient remains to be clarified" Peyromaure et al, Urology 64(5): 1037-1041, 2004. However, as is the case with all pharmaceutical and therapeutic inventions, the standard of enablement does not require that the optimum dosage and frequency be known in order for a patent to issue. Under the standard that dosages, frequency, and location of treatment must be disclosed for a therapy to be patentable, no drug or therapy for treating a particular condition would be patentable without demonstrating clinical efficacy, which can only be achieved by human trials. That is, no patent could be granted on any therapy unless the application contained clinical data showing the efficacy of the compound together with its final dosage regimen and galenic form.

Furthermore, "it is improper for Office personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981)." MPEP § 2107.03.

Applicant respectfully submits that the directive of MPEP § 2107.03 indicates that it would not be reasonable in the field of pharmaceuticals and likewise would not be reasonable in the biotechnology field to require the information the Office Action specifies. Accordingly, the Office Action does not establish a prima facie case that the method cannot be implemented by one of ordinary skill in the art given the disclosure of the specification.

VII. REJECTION OF CLAIMS 46 AND 52 UNDER 35 U.S.C. §§ 102 and 103(a)

The Office Action rejected claims 1 and 31-33 under 35 U.S.C. § 102(b) as being anticipated by Chancellor. The Office Action rejected claims 1, 31-33, and 46 under 35 U.S.C. § 102(e) as being anticipated by Chancellor. The Office Action rejected claims 1, 31-32, and 46 under 35 U.S.C. § 102(a) as being anticipated by Chancellor. The Office Action rejected claims 1, 31-32, and 46 under 35 U.S.C. § 103(a) as unpatentable over Chancellor in view of Yiou in further view of Yokoyama in still further view of Sanberg.

A. Rejections Of Claim 1 Under § 102

Claims 31-33 and 46 are dependent directly or indirectly on claim 1. Claim 1 recites a method for a functional treatment of urethral sphincters in a human. The method administers, to the human, myoblasts obtainable by culturing the myoblasts in a cell culture medium. The culture medium includes at least one of a serum of human origin, a serum fraction of human origin, a serum of animal origin, and a serum fraction of animal origin. The culture medium also includes at least one of insulin and a derivative of insulin. The culture medium also includes at least one compound selected from the class of antioxidants and vitamins. The culture medium also includes a glucocorticoid.

Applicant respectfully submits that claim 1 is not a product-by-process claim. By definition, a product-by-process claim is a product. "A product-by-process claim, which is a

product claim that defines the claimed product in terms of the process by which it is made..." MPEP § 2173.05(p). Claim 1 is a method claim, not a product claim. There is no such category as a method-by-process claim for the simple reason that all method claims disclose a process. Accordingly, novelty can be conferred by parts of the method that differ from the cited references. Therefore, the burden remains on the Examiner to find references that disclose the all the limitations of the method of claim 1.

The current Office Action does not identify all the elements and limitations of claim 1 in the cited references. For example, the Office Action does not identify a reference for a growth medium with anti-oxidants or vitamins. Accordingly, the Office Action does not meet the *prima facie* burden of demonstrating anticipation.

Furthermore, the myoblasts created and used in the claimed therapy method are not the same as any myoblasts of the cited references. Applicant respectfully submits that none of the media in the cited references include insulin and glucocorticoid. The use of a medium with glucocorticoid is supported in the specification (e.g., Example 9 of the specification). Example 9 of the specification compares the media of some embodiments with other media. The experiment described demonstrates that the media supplemented with insulin and dexamethasone (which is a glucocorticoid) results in a greater number of myogenic cells than media without insulin and dexamethasone. Consequently, the combination results in an increase of the therapeutic potential of the myoblasts cultured in it. Thus, the myoblasts cultured in the claimed media possess a quality which distinguishes them from any myoblasts cultured according to the cited references.

As the Office Action indicated (*see*, Office Action, page 12), in a product by process claim (which this claim is not) the recitation of process limitations are positively limiting when the process imparts a novel property to the claimed product. Accordingly, even if this were a

claim for a product, rather than a claim to a therapeutic method, the claim would be valid over the cited references.

B. Rejection Of Claim 1 Under § 103(a)

Applicant respectfully submits that the cited references do not disclose the limitations of claim 1. None of the elements cited in the Office Action from Yiou, Yokoyama, and Sandberg are present in claim 1. Furthermore, the piecemeal hindsight combination of all of the cited references does not anticipate claim 1. Yiou does not disclose the use of specific media to confer improved properties on the myoblasts and does not disclose any media with insulin and a glucocorticoid. Yokoyama likewise does not disclose, teach, or suggest culturing the cells in a specific media containing insulin and a glucocorticoid as claim 1 does. Sandberg describes methods for culturing cells, but also does not disclose, teach, or suggest culturing the cells in a specific media containing insulin.

Additionally, Applicant respectfully submits that it would not be obvious to one of ordinary skill in the art to combine the cited references to produce the limitations of claim 1. The number of possible growth media is incalculably large, and nothing in the known art provides that the particular combination recited in claim 1 would produce the results obtained and disclosed in the specification.

Accordingly, Applicant respectfully submits that claim 1 is patentable over the cited reference for at least the reasons cited above. As claims 31-33 and 46 and withdrawn claims 34-45 and 47 depend directly or indirectly from claim 1, they are valid for at least the same reasons as claim 1.

VIII. REJECTION OF CLAIMS 48 AND 52 UNDER 35 U.S.C. §§ 102 and 103(a)

The Office Action rejected claim 48 under 35 U.S.C. § 102(a), 102(b), 102(e) as being anticipated by Chancellor. The Office Action rejected claim 52 under 35 U.S.C. § 102(a), 102(e) as being anticipated by Chancellor. The Office Action rejected claims 48 and 52 under 35 U.S.C. § 103(a) as unpatentable over Chancellor in view of Yiou in further view of Yokoyama in still further view of Sanberg.

Applicant respectfully submits that claim 48 is valid for at least the same reasons detailed above with respect to claim 1. Claim 48 is a method claim, not a product claim. Accordingly, all limitations must be shown for a rejection to be valid. In addition to the reasons cited with respect to claim 1 above, the Office Action does not provide a reference to a method like claim 48 in which the cell growth medium contains bFGF, FGF-2, or FGF-10. The Office Action also does not provide a reference to a method like claim 48 that contains a lipophosphatidic acid, EGFs, heregulins, thrombin, PDGF, thyroid hormones, or LIF. Therefore, the Office Action does not meet the *prima facie* burden of showing that claim 48 is unpatentable.

The cited references alone or in hindsight, piecemeal combination do not provide all limitations of the claims (e.g., use of a medium with glucocorticoid and insulin in the method described in the claim). Furthermore, there is no reason that it would be obvious to combine the cited references.

Accordingly, Applicant respectfully requests that the §§ 102 and 103(a) rejections of claims 48 and 52 be withdrawn and that claims 48, 50, 52, and 53 be allowed.

IX. REJECTION OF CLAIMS 48 AND 52 UNDER 35 U.S.C. §§ 102 and 103

The Office Action rejected claim 54 under 35 U.S.C. § 102(a), 102(b), 102(e) as being anticipated by Chancellor. The Office Action rejected claim 54 under 35 U.S.C. § 103(a) as

unpatentable over Chancellor in view of Yiou in further view of Yokoyama in still further view of Sanberg.

Applicant respectfully submits that claim 54 is valid for at least the same reasons detailed above with respect to claim 1. Claim 54 is a method claim, not a product-by-process claim. The burden remains on the Examiner to show all limitations. The Office Action does not make a prima facie case for rejections under §§ 102 or 103(a). The cited references alone or in hindsight, piecemeal combination do not provide all limitations of the claims (e.g., use of a medium with glucocorticoid and insulin in the method described in the claim). Furthermore, there is no reason that it would be obvious to combine the cited references.

Accordingly, Applicant respectfully requests that the §§ 102 and 103(a) rejections of claim 54 be withdrawn and that claim 54 be allowed.

CONCLUSION

Applicant believes that no additional fee is required for the submission of this amendment, beyond the already submitted fee for extension of time. However, in the unlikely event that the Commissioner determines that additional fees, extension and/or other relief is required, Applicant petitions for any required relief in connection with the filing of this amendment and associated documents to **Deposit Account No. 50-3804** referencing CABH.P0002.

Respectfully submitted,

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